UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

08/746361

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY DOCKET NO.
08/746,361	11/08/96	ANDERSON	

EXAMINER	
GAMBEL, P	

ART UNIT	PAPER NUMBER
1644	27

021839
BURNS DOANE SWECKER & MATHIS
P O BOX 1404
ALEXANDRIA VA 22313-1404

HM12/0602

DATE MAILED: 06/02/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 1/3/00 ; 1/18/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 29-37 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 29-37 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

1. Claims 1-28 have been canceled previously.
Claims 29-37 are pending and being acted upon presently.

2. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 previously sent in Paper No. 7.
Formal figures will be submitted upon indication that this application is allowable.

3. Upon consideration of applicant's arguments, in conjunction with the signed Anderson declaration under 37 C.F.R. § 1.132, filed 1/18/00; the previous rejection under 35 U.S.C. § 102(e) as being anticipated by de Boer et al. (U.S. Patent No. 5,747,034) has been obviated; given that the referenced B7-24 antibody inhibits both CTLA-4/CD28 binding.

4. Claims 29-37 are rejected over by de Boer et al. (U.S. Patent No. 5,747,034) and Linsley et al. (U.S. Patent No. 5,770,197) in view of art-known procedures and motivation to generate recombinant antibodies (e.g. humanized, chimeric or primatized) for diagnostic and therapeutic regimens as acknowledged on pages 15-20 and 24-27 of the specification (e.g. Newman et al. Biotechnology, 1992).

Applicant's arguments, of record, have been fully considered but are not found convincing as they apply to rejection under obviousness for B7-1-specific antibodies which inhibit binding for CD28 but not CTLA-4.

Applicant's arguments in conjunction with the signed Anderson declaration under 37 C.F.R. § 1.132, filed 1/18/00, appear to center on the issue that while the referenced B7-1-specific antibodies bind a distinct epitope, this does not support the proposition that the referenced antibodies do not inhibit B7.1/CTLA-4 interactions, as claimed. In support, applicant argues that other prior B7-1 antibodies which bind distinct epitopes inhibit both B7.1/CD28 and B7.1/CTLA-4 interactions, which contrasts with the claimed antibodies which only inhibit the B7.1/CD28 interaction but not the B7.1/CTLA-4 interaction. Therefore, applicant has argued that the prior art neither teach nor suggest with an expectation of success B7.-1-specific antibodies which do not inhibit the B7.1/CTLA-4 interaction.

With respect to obviousness, applicant argues that de Boer et al. does not provide sufficient motivation and expectation of success in generating B7.1 -specific antibodies inhibit the B7.1/CD28 interaction. Applicant has argued that B7 binds both CTLA-4/CD28, which have a high degree of homology; therefore antibodies that bind B7 and inhibit its interaction with CD28 would also be expected to inhibit interaction with CTLA-4.

It is acknowledged that applicant has provided objective evidence by side-by-side testing to show that the prior art B7-1-specific antibodies do not inhibit the B7.1/CTLA-4 interaction or would be expected to inhibit both CTLA-4/CD28 and CTLA-4/CD2, particularly with respect to the antibodies taught by de Boer et al.

However, given the known exquisite specificity of antibodies and that CTLA-4/CD28 are distinct molecules albeit homologous; one of ordinary skill in the art at the time the invention was made would have been motivated to select recombinant B7.1-specific antibodies as diagnostic and therapeutic agents in treating human immunoregulatory disorders.

It is noted that de Boer et al. indicate that while the B7 molecules as well as CTLA-4 and CD28 are involved in cell interactions and signaling; there are distinct differences in their properties as well as the binding and inhibitory properties of various molecules. See Detailed Description of the Invention, including columns 5-6. Therefore, de Boer clearly recognizes differences between CD28 and CTLA-4 as they apply to their interaction with B7 at the time the invention was made.

Simlarly, Linsley et al. ('197) teaches the role of the B7 molecules as well as CTLA-4 and CD28 in cell signaling and various molecules including antibodies to block their functions (see entire document(). Also, Linsley et al. Teach anti-B7 antibodies may be used to bind to B7 to inhibit interactions of CD28-positive or CTLA-positive T cells with B7 positive cells (see column 15, paragraph 7).

One of ordinary skill in the art at the time the invention was made would have been motivated to select anti-B7 antibodies with differential properties of blocking binding to CD28 and CTLA-4 for various detection, diagnostic and therapeutic uses. Given that CD28/CTLA-4 were known to structurally and functionally distinct; the ordinary artisan would have had an expectation of success in generating antibodies which inhibit B7-CD28 binding and not B7-CTLA-4 binding at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 29-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-37 of copending application USSN 08/487,550. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are species/subgeneric of the instant claimed antibodies/composition and that the copending claimed antibodies are the exemplified antibodies of the instantly claimed antibodies.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 29-37 are directed to an invention not patentably distinct from claims 27-37 of commonly assigned USSN 08/487,550 for the reasons above.

Commonly assigned 08/487,550, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. § 103 if the commonly assigned case qualifies as prior art under 35 U.S.C. § 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 C.F.R. § 1.78© to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103 based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g).

8. Claims 29-37 are provisionally rejected 35 U.S.C. § 102(e) as anticipated by or 35 U.S.C. § 103 as being obvious over copending application Serial No. 08/487,550.

Copending application Serial No. 08/487,550 has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. § 102(e) if patented. This provisional rejection under 35 U.S.C. § 103 is based upon a presumption of future patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 C.F.R. § 1.132 that any unclaimed invention disclosed in the copending application was derived from the inventor of this application and is thus not the invention "by another", or by a showing of a date of invention prior to the effective U.S. filing date of the copending application under 37 C.F.R. § 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Copending USSN 08/487,550 teaches B7-1-specific antibodies which appear to have the same or nearly the same properties encompassed by the instant claims. The burden is on the applicant to establish a patentable distinction between the claimed and referenced antibodies.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, Ph.D.
Primary Examiner
Technology Center 1600
June 1, 2000